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FAX TRANSMISSION

Total 9 pages, including cover sheet

To: Commissioner for Patents
U.S. Patent and Trademark Office

Fax no.: **(571) 273-8300**

From: David L. Fitzgerald, Reg. no. 47,347
Tel. (202) 736-8818

Date: **28 April 2006**

Re:

Serial No.:	**09/911,703**	Group Art Unit:	1644
Confirmation No.:	4927	Examiner:	R. Schwadron
Filed:	25 July 2001		
Applicant:	Darrell R. ANDERSON et al.		
For:	Anti-CD20 Antibodies		

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

I CERTIFY THAT THE FOLLOWING DOCUMENTS ARE BEING TRANSMITTED TO THE USPTO AT FAX NUMBER (571) 273-8300 ON THE DATE SHOWN:

- Fee transmittal with petition for extension (1 page)
- Petition under § 1.181(a) re Sequence Rules (7 pages)

SIGNATURE

David L. FITZGERALD
PRINTED NAME

28 Apr 06
DATE

FEE TRANSMITTAL		Serial Number	09/911,703
		Attorney Docket No.	27693-01008
		Filing Date	25 July 2001
		First Named Inventor	Darrel R. ANDERSON
		Group Art Unit	1644
AMOUNT ENCLOSED	$ 120.	Examiner Name	R. Schwadron

FEE CALCULATION

CLAIMS AS AMENDED	Claims Remaining After Amendment	Previously Paid For	Number Extra	Rate	Calculations
TOTAL CLAIMS	42	- 47 =	0	X $50.00 =	0
INDEPENDENT CLAIMS	2	- 7 =	0	X $200.00 =	0
MULTIPLE DEPENDENT CLAIM FEE (first presentation, $360)					0
The most recent Office letter sets an original due date of 28 March 2006. Applicant petitions for an extension of **1 month** to cover the date this petition is filed, for which the fee is $450					$ 120.
Information Disclosure Statement (§ 1.17(p))					0
Total of above Calculations =					$ 120.
Reduction by 50% for filing by small entity (37 CFR 1.9, 1.27 & 1.28)					
TOTAL FEES DUE =					**$ 120.**

METHOD OF PAYMENT

- ☐ Check enclosed as payment.
- ☒ **Charge "TOTAL FEES DUE" to the Deposit Account No. below.**
- ☐ No payment is enclosed and no charges to the Deposit Account are authorized at this time (unless specifically required to obtain a filing date).

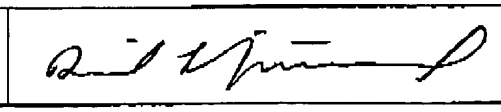
GENERAL AUTHORIZATION

- ☒ If the above-noted "AMOUNT ENCLOSED" is not correct, the Commissioner is hereby authorized to credit any overpayment or charge any additional fees necessary to:

  Deposit Account No. **18-1260**

  Deposit Account Name **Sidley Austin Brown & Wood**

- ☒ The Director is also authorized to credit any overpayments or charge any additional fees required under 37 CFR § 1.16 or § 1.17 during the pendency of this application to maintain its pending status.

SUBMITTED BY:	David L. Fitzgerald	Reg. No.	47,347
Signature		Date	28 Apr 06

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28 APRIL 2006

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Serial no. 09/911,703 Attorney Docket no. 27693-01008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. § 1.181(a)
REGARDING A REQUIREMENT UNDER § 1.821 *et seq.* (SEQUENCE RULES)

Sir:

Applicant petitions under 37 C.F.R. § 1.181(a) from a requirement of the primary examiner regarding the information set forth in a sequence listing filed under § 1.821 *et seq.* As provided by M.P.E.P. § 1002.02(c)(2), the Director has delegated authority to decide this petition to the Directors of Technology Center 1600.

The requirement in question was first set forth in an Office letter mailed on 2 November 2005. Applicant requested reconsideration of the requirement in a letter filed on 2 December 2005. In an Office letter mailed on 28 February 2006, the primary examiner held that the reply filed on 2 December 2005 was *bona fide* but nonresponsive. This petition is filed within two months of the mailing date of the notice from which relief is requested (*i.e.*, the 28 February Office letter). Accordingly, this petition is timely as required by 37 C.F.R. § 1.181(f), second sentence.

Applicant believes that this is a "no-fee" petition. However, should a petition fee under 37 C.F.R. § 1.17 or any other fee be required for consideration of this petition, the Director is requested to charge the appropriate amount(s) to our Deposit Account No. 18-1260.

The Office letter mailed on 28 February 2006 set a one-month period for response, with extensions of time available under 37 C.F.R. § 1.136(a). A petition to extend the period for response by one month, to and including 28 April 2006, accompanies this petition. Accordingly, the application is pending as of the date of this petition. Applicant understands that the period for response continues to run from the mailing date of the last Office letter until such time as the Office vacates, or applicant complies with the outstanding requirement. § 1.181(f).

Facts

1. This application contained a paper-copy sequence listing as filed. Included in the sequence listing are the sequences of four PCR primers, also set forth in the specification at pages 40 and 41. Both the specification and the original paper-copy sequence listing indicate the primers that are antisense. The antisense primers are listed in the as-filed sequence listing as SEQ ID NOs: 4 and 7.

2. An electronic-copy sequence listing, prepared in conformance with the technical requirements of the "old" sequence rules, was entered in the file wrapper on 11 January 2002. That listing included the indication that SEQ ID NOs: 4 and 7 were antisense sequences.

3. In response to various requirements, substitute electronic-copy sequence listings, prepared in accord with the standards of 37 C.F.R. § 1.821 *et seq.* and WIPO Standard ST.25, were filed on 30 March 2004, 15 December 2004, and 12 August 2005. None of these sequence listings indicated the sense or antisense orientation of the originally disclosed primers.

4. The primers originally disclosed as SEQ ID NOs: 4 and 7 are listed as SEQ ID NOs: 9 and 11, respectively, in the current sequence listing. The sequences *per se* are otherwise identical to those in the original specification and sequence listing.

5. On 2 November 1995, the Office mailed a "Notice to Comply ..." indicating that the sequence listing filed on 12 August 2005 failed to comply with 37 C.F.R. § 1.821 *et seq.* and requiring a substitute sequence listing. The explanation of the deficiency was as follows:

> Original SEQ. ID. No. 4 and 7 (now SEQ. ID. No. 9 and 11) were disclosed as antisense in the originally filed sequence listing, but are not disclosed as antisense in the currently filed listing.

6. Applicant filed a reply on 2 December 2005. The reply explained that an indication of antisense orientation of listed sequences would be placed under field <223> and argued why that field was optional under 37 C.F.R. § 1.823 with respect to such information, not mandatory. Applicant requested that the examiner vacate the requirement mailed on 2 November 2005.

7. In a letter mailed on 28 February 2006, the examiner held applicant's reply nonresponsive and repeated the requirement for a new sequence listing. The examiner explained the reason for the holding:

> Regarding applicant[']s comments, 37 CFR section 1.823(b) discloses that section <223> is mandatory when the organism is "artificial sequence". However, said section does not disclose that description of the sequence in section <223> as antisense is optional. Section <223> (as per 1.823(b)) discloses that said section should contain "Other relevant information; four lines maximum". While 1.823(b) does not specifically elucidate the nature of said "Other relevant information", the previously filed sequence listing indicated that the sequences under consideration were antisense. Thus, the previously filed sequence listing specifically designated relevant information regarding said sequences wherein said information would be encompassed by the "Other relevant information; four lines maximum" as per listed in section <223>.

8. In compliance with M.P.E.P. § 713.04, applicant notes that the outstanding requirement was discussed briefly during a personal interview on 29 March 2006 between Examiner Schwadron and applicant's representatives, Jeffrey Kushan and David Fitzgerald. (The greater part of the interview involved other cases pending before the examiner.) The examiner and applicant's attorneys did not reach agreement as to whether the requirement was appropriate, and procedural considerations for responding were discussed.

Discussion

Applicant maintains that the requirement for a substitute sequence listing, originally set forth in the Office letter mailed 2 November 2005 and restated in the letter mailed 28 February

2006, is improper and should be vacated. The examiner does not correctly apply the requirements of 37 C.F.R. § 1.823.

The information that is required to appear in the header fields of sequences in a sequence listing is specified at 37 C.F.R. § 1.823. The identity and content of the numbered header fields, according to WIPO Standard ST.25, are set forth in the table that is included in § 1.823(b). An indication that a DNA sequence is sense or antisense would appear as a miscellaneous feature in fields <220> to <223>. The relevant portion of the table is presented below.

§ 1.823 CONSOLIDATED PATENT RULES

Numeric Identifier	Definition	Comments and format	Mandatory (M) or Optional (O)
<220>	Feature.....	Leave blank after <220>. <221-223> provide for a description of points of biological significance in the sequence.	M, under the following conditions: if "n," "Xaa," or a modified or unusual L-amino acid or modified base was used in a sequence; if ORGANISM is "Artificial Sequence" or "Unknown"; if molecule is combined DNA/RNA.
<221>	Name/Key.....	Provide appropriate identifier for feature, preferably from WIPO Standard ST.25 (1998), Appendix 2, Tables 5 and 6.	M, under the following conditions: if "n," "Xaa," or a modified or unusual L-amino acid or modified base was used in a sequence.
Numeric Identifier	Definition	Comments and format	Mandatory (M) or Optional (O)
<222>	Location.....	Specify location within sequence; where appropriate state number of first and last bases/amino acids in feature.	M, under the following conditions: if "n," "Xaa," or a modified or unusual L-amino acid or modified base was used in a sequence.
<223>	Other Information.....	Other relevant information; four lines maximum.....	M, under the following conditions: if "n," "Xaa," or a modified or unusual L-amino acid or modified base was used in a sequence; if ORGANISM is "Artificial Sequence" or "Unknown"; if molecule is combined DNA/RNA.

As provided by § 1.823(b), fifth and sixth sentences:

The submission of those items of information designated with an "M" is mandatory. The information of those items designated with an "O" is optional.

Thus, as indicated in the table at § 1.823(b), information fields <220> to <223> are mandatory only under the following conditions:

(i) a residue is a "wildcard," modified, or unusual amino acid or nucleotide base;

(ii) the ORGANISM is an artificial sequence or unknown; or

(iii) the listed sequence represents a combined DNA/RNA molecule.

Section 1.823(b) does not specify that an indication as to whether a sequence is sense or antisense is mandatory. Accordingly, the information is not mandatory; *i.e.*, it is optional. The sequence listing filed on 12 August 2005 does not fail to comply with the sequence rules for omitting this information. That sequence listing fully complies with 37 C.F.R. § 1.821 *et seq.*

The examiner reasons that because the fact that SEQ ID NOs: 9 and 11 are antisense is "other relevant information," inclusion of the information in the sequence listing *per se* is mandatory. The examiner holds that because the rule does not state that inclusion of this information is optional, the information must be mandatory because it is "relevant."

The rule provides otherwise. Section 1.823 enumerates the specific kinds of information which are required to be listed. In every other case, in accord with the ordinary meaning of "optional" and "mandatory," the information is not required. As stated in the rule package that implemented the ST.25 standard and promulgated the relevant language of current § 1.823:

> The "Other Information" line in the Features section, which is numeric identifier <223> in § 1.823, provides for a description of a sequence. While completion of this section is only mandatory when the sequence contains "n", "Xaa", a modified or unusual L-amino acid or a modified base, it is frequently completed in other circumstances.

"Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures," 63 Fed. Reg. 29621, 29633 (1 June 1998) (emphasis added).

"Other relevant information" that the applicant may wish to include in the sequence listing should be placed in fields <220> to <223>. However, not all relevant information is mandatory, even if the fields "are frequently completed in other circumstances" when the

information is not required. The only "relevant information" that is mandatory is identified in the rule.

> Indeed, as originally promulgated, 37 C.F.R. § 1.823(b) provided, in relevant part:
>
> The "Sequence Listing" shall, except as otherwise indicated, include, in addition to and immediately preceding the actual nucleotide and/or amino acid sequence, the following items of information. ... The submission of those items of information designated with an "M" is mandatory. The submission of those items of information designated with an "R" is recommended, but not required.
>
> ...
>
> (A) DESCRIPTION (four lines maximum):
>
> ...
>
> (iv) ANTI-SENSE (yes/no - R):

See 55 Fed. Reg. 10230 (1 May 1990). When the current version of the rule was proposed, the Office explained:

> Large portions of Section 1.823(b) are proposed to be deleted to lessen the burden on applicants and to eliminate collections of material which is of limited use to the Office. ...
>
> It is proposed that the recommended designation be eliminated, leaving only mandatory and optional elements.

See 61 Fed. Reg. 51855 (4 October 1996), 1191 *O.G. Pat. Off.* 168 (29 October 1996). Thus, information concerning strand orientation was never required, and the Office views such information as being "of limited use." Current 37 C.F.R. § 1.823 does not provide authority for the examiner to impose the present requirement for a new sequence listing.

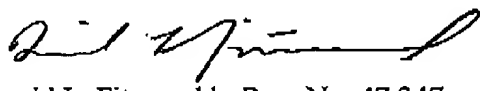
Applicant notes that the sequence listing filed on 12 August 2005 does not raise a question of new matter with respect to the orientation of SEQ ID NOs: 9 and 11. These sequences (original SEQ ID NOs: 4 and 7) are clearly indicated as antisense primers in the original specification at page 40, line 33, and page 41, line 26, respectively. That information remains in the specification as currently amended.

Applicant also notes that the response filed on 12 August 2005 was a complete reply to the previously outstanding requirement under 37 C.F.R. § 1.111. The interval between 12 August 2005 and the date that this petition is submitted thus does not correspond to a failure on the part of the applicant to engage in reasonable efforts to conclude prosecution within the meaning of 37 C.F.R. § 1.704. For the same reason, any time between the date that is four months after 12 August 2005 and the date the Office mails a communication under 35 U.S.C. § 132 or § 151 constitutes an examination delay under 37 C.F.R. § 1.703(a)(2).

Conclusion

Applicant respectfully requests that the Office vacate the requirement set forth in the letter mailed on 2 November 2005 and restated in the letter mailed on 28 April 2006.

Respectfully submitted,



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28 Apr 06

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